OUT OF SPECIFICATIONS (OOS) AND CONDUCTING EFFECTIVE INVESTIGATIONS

Background

Deficiencies in out-of-specifications (OOS) investigations continue to be the major cause of non-compliance and have been identified in most audits conducted in the pharmaceutical industry. The FDA requires that all OOS results must be investigated; thus, an effective and compliant quality management system requires well-documented, thorough investigations for OOS. Key challenges for many pharmaceutical organisations are having a clear understanding of regulatory expectations on how to handle OOS and out-of-trends (OOT). Ineffective investigations and inappropriate root-cause analysis results in a non-compliant facility with inefficient processes and throughput.

This training programme aims to discuss regulatory compliant approaches on addressing OOS and OOT investigations effectively as per "**Guidance for Industry"** issued by the FDA. As testing becomes critical to determine the cause of OOS results, investigation processes will be discussed during the training programme and it will also cover procedures that will minimize OOS and make it easily feasible to identify OOTs. It will also make attendees familiar with the documentation system as well as Corrective and Preventive Actions (CAPA) activities.

Learning Objectives

1. Understand regulatory expectations for OOS investigations
2. Define quality management system for reporting data
3. Build robustness into the production and analytical procedures to prevent OOS occurrences
4. Build compliance (as per regulatory standards) into the investigation process to minimize OOS
5. Define and monitor Corrective and Preventive Actions (CAPAs)

Target group

- Production or Manufacturing
- Research and Development
- Quality Control (QC)
- Quality Assurance
- Regulatory Affairs
- Researchers (Clinical and Academia)

Programme

The presentation will consist of a presentation emphasizing practical approaches of conducting effective investigations as per regulatory requirements; practical cases studies relating to production and analytical processes emphasizing the following:

Day 1: 04 November 2020 (9am – 12:30pm)

a) Definition of OOS and OOT
b) General OOS procedure
c) Quality Risk Assessment
d) Deviations
e) Identifying and assessing OOS test results

Day 2: 05 November 2020 (9am – 12:30pm)

1. Phase I and II investigations
2. Determine CAPA and monitoring processes
3. Understand cross-functional investigation
4. Determine key performance indicators (KPI) to monitor process improvement
5. Establish documentation and performance metrics

Presenter

Mbonisi is a qualified pharmacist and formulation scientist with a great passion for the pharmaceutical industry with extensive research background and has served in well renowned organizations. His experience includes medicine systems consultancy; technical operations; operations management; pharmaceutical development; process engineering; analytical method development; regulatory affairs; research and academia.

Mbonisi holds a postgraduate degree and a vast number of courses from various institutes and thus he well versed with current techniques, skills and standards in the pharmaceutical industry. He holds a Bachelor of Pharmacy (B.Pharm) degree, Master of Science (M.Sc) in Pharmaceutical Chemistry degree from Rhodes University in collaboration with University of Tiaret. Mbonisi is currently pursuing a Doctor of Philosophy (Ph.D) degree at the University of Witwatersrand focusing on the application of mathematical modelling in pharmaceutical development for different drug delivery systems. To date he has published three journal articles and co-authored one book chapter.